April 2014

RX News Bulletin

Bureau of Narcotics & Dangerous Drugs

Missouri Department of Health and Senior Services

health.mo.gov/safety/bndd/index.php

DEA Proposes Rules to Move Hydrocodone Combination Products to Schedule II

The United States Drug Enforcement Administration (DEA) has published a Notice of Proposed Rulemaking in the Federal Register. The proposed rule seeks to move hydrocodone combination drug products out of Schedule III and moves these drug products into Schedule II.

- Written prescriptions would require an original signature.
- They could only be faxed for hospice or LTC patients.
- No refills would be authorized for these drugs.
- In Missouri, Schedule II medications have to be locked in a safe or cabinet. Members of the public are invited to submit comments through the website www.regulations.gov.

Comments may be submitted in writing or electronically. These comments must be postmarked by 11:59 p.m. Eastern Time on April 27, 2014.

National Governor's Association Focuses on Prescription Drug Abuse

State Governors from the United States recently held their 2014 Winter meeting. They have had a year-long initiative to address comprehensive, coordinated plans to combat the public health and safety crisis. Governors attended a session titled, "Battling an Epidemic: State Efforts to Combat Prescription Drug Abuse."

The association recently released a document titled, "Findings from Reducing Prescription Drug Abuse: Lessons Learned from an NGA Policy Academy." The information addresses leadership; prescribing behavior needs to change; effective disposal of unwanted medications; prescription drug monitoring programs; public education; treatment for drug abuse; and best policies and practices. For more information about their Prescription Drug Abuse Project you may visit their website at www.nga.org/cms/Rx.

Inside

DEA Proposes Rules to Move Hydrocodone Combination Products to Schedule II 1

National Governor's Association Focuses on Prescription Drug Abuse 1

Mid-Level Practiioners and Their Authority in Hospitals 2

Drug Distributors Are Reporting Suspicious Purchase Orders and Requests 3

Drug Take Back Day 4

Mid-Level Practitioners and Their Authority in Hospitals

The Bureau of Narcotics and Dangerous Drugs (BNDD) has received multiple inquiries from hospital pharmacists wanting to verify exactly what Advanced Practice Nurses (APRNs) and Physicians' Assistants (PAs) may do in a hospital. The BNDD is providing the chart below to describe what activities may take place and what activities may not take place.

Drug Information	Advanced Practice Nurses	Physicians' Assistants
Schedule II	No authority at all. May not give orders. May not alter, amend, or discontinue an existing order. They may receive an order from a doctor and then enter it into a system as a physician's order. The physician must come around afterward and sign off on this order they initially approved.	No authority at all. May not give orders. May not alter, amend, or discontinue an existing order. They may receive an order from a doctor and then enter it into a system as a physician's order. The physician must come around afterward and sign off on this order they initially approved.
Schedule III Non-opiates	Full authority to order and prescribe Schedule III drugs that are not opiates. No restrictions; their authority is the same as a physician.	Different than APRNs. They are limited to a 5-day or 120-hour supply of all Schedule III drugs, no matter what type they are. No refills are allowed. A new order could be given every 120 hours.
Schedule III Opiates	They may order and prescribe Schedule III opiate/narcotics, however they are limited to a 5-day or 120-hour supply. No refills are allowed. A new order could be given every 120 hours.	Same as above; they are limited to a 5-day supply or a 120 hours with no refills. A new order could be given every 120 hours.
Schedules IV & V	Full authority with no restrictions. They may prescribe and order. Once issued, a prescription is valid for 6 months from the date written. A single prescription may only be for a maximum of a 90-day supply.	Full authority with no restrictions. They may prescribe and order. Once issued, a prescription is valid for 6 months from the date written. A single prescription may only be for a maximum of a 90-day supply.
Family Members	No controlled substance authority for family members, for several generations, including in-laws.	No controlled substance authority for family members, for several generations, including in-laws.

Facilities should have a system in place to track the ordering of mid-level practitioners. They can be issued a password to order with full authority in Schedules IV and V. Their Schedule III activities should be limited according to their license type. They should not be entering their own orders, in their own names, for Schedule II medications. Schedule II medications may only be authorized by a physician and should be entered as authorized by a doctor.

Some hospitals give mid-level practitioners one identification number for their own activities under their personal license, but then they give them a second password or identification number to use when they are entering Schedule II orders for physicians.

Drug Distributors Are Reporting Suspicious Purchase Orders and Requests

Both federal and state regulations require all drug distributors to have security controls in place to detect and prevent the diversion of controlled substances. As practitioners and pharmacies place orders to their suppliers, the distributors are required to review each order, make good faith inquiries, and report suspicious orders to both the state of Missouri and the United States Drug Enforcement Administration.

When a practitioner or pharmacy is deemed to be ordering a suspicious amount, an excessive supply, or an amount that does not appear to be congruent and consistent with the number of practitioners in the area who are treating the available population, the distributors will usually deny the sale and report the requested transaction to authorities.

Investigations by authorities have been moving from both ends of the supply and distribution chain.

- When a disciplinary action is taken against a prescriber, the authorities look next to the pharmacies that dispensed the prescriptions. This is to insure that the pharmacies were taking normal steps to act as a gatekeeper.
- Reviews also extend up to the distributor level to see the amounts of drugs sold to those pharmacies and practitioners should have triggered a review.
- During inspections the authorities are providing more emphasis to distributors to review and monitor their sales for suspicious patterns.

Upon reviewing the DEA website at www.deadiversion.usdoj.gov, the following information is provided to all registrants:

- **Good Faith Inquiry**
  Before distributing a controlled substance to any person whom the registrant does not know to be registered to possess the controlled substance, the registrant must make a good faith inquiry either to DEA or to the appropriate state controlled substances licensing or registration agency, if any, to determine that the person or company may lawfully possess the controlled substances.

- **Suspicious Orders**
  The registrant must design and operate a system to disclose suspicious orders of controlled substances. The registrant must inform the appropriate DEA Field Office of suspicious orders immediately upon discovery. Such orders include, but are not limited to, orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.
- **Controlled Substance Samples**
  Complimentary samples of any controlled substance may not be distributed unless the following conditions are met:
  1. The distributor has a prior written request from the registrant which includes the customer's name, address, registration number, and name and quantity of the specified controlled substance;
  2. The controlled substance is to be used to meet the legitimate medical needs of patients; and
  3. Reasonable quantities are requested.

Mark Your Calendars!

Drug Take-Back Day is April 26

The United States Drug Enforcement Administration (DEA) is sponsoring a drug take-back day on Saturday, April 26, 2014. Individuals may take unwanted prescription drugs to their participating law enforcement agencies. If you want to encourage your local law enforcement agencies to participate in this program, please have your local law enforcement agencies call the St. Louis DEA office at (314) 538-4600. On October 13, 2013, the state of Missouri had 134 law enforcement agencies collecting drugs at 190 locations. During that take-back event, the state collected 19,901 pounds of unwanted pharmaceuticals.

Missouri Department of Health and Senior Services, Bureau of Narcotics and Dangerous Drugs, 3418 Knipp Drive, PO Box 570, Jefferson City, MO 65102; (573) 751-6321; (573) 751-2569 fax; bndd@health.mo.gov; health.mo.gov/safety/bndd/index.php

Alternate forms of this publication for persons with disabilities may be obtained by contacting the Missouri Department of Health and Senior Services, BNDD, P.O. Box 570, Jefferson City, MO, 65102, (573) 751-6321. Hearing- and speech-impaired citizens can dial 711. EEO/AAP services provided on a nondiscriminatory basis.